Bill Draft 2011-TG-14:
Reg. Compliance/Product Liability Defense.

2011-2012 General Assembly

Committee:	Senate Judiciary I	**Date:**	February 20, 2012
Introduced by:		**Prepared by:**	Bill Patterson
Analysis of:	2011-TG-14		Committee Counsel

SUMMARY: Bill Draft 2011-TG-14 establishes a rebuttable presumption in any product liability action that a drug was safe and effective for its approved use if it complied with FDA approval at the time it left the manufacturer's or seller's control, unless the manufacturer or seller obtained FDA approval by bribery or by withholding or misrepresenting material facts relevant to the harm to the claimant, or sold the drug after FDA recall or withdrawal of approval. The defense would not bar False Claims Act claims unless they are based on allegations that the drug was not safe or effective or that the manufacturer's warnings were inadequate.

CURRENT LAW AND BILL ANALYSIS:

Current Law: Under current law, in determining whether any product manufacturer is liable for the product's inadequate design or formulation, the trier of fact must consider, among other things:

- The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer[1]
- The extent to which the labeling for a prescription or nonprescription drug approved by the FDA conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer[2]

Neither of these considerations gives rise to a presumption under current law.

Bill Analysis: Section 1 of the bill enacts G.S. 99B-12, applicable in any product liability action[3], establishing a rebuttable presumption that a drug was safe and effective for its approved use if the FDA approved it for safety and efficacy and its labeling was in compliance with FDA approval at the time it left the control of the manufacturer or seller. This presumption may be rebutted only by clear and convincing evidence.

The defense is not available if the plaintiff establishes by a preponderance of the evidence that the manufacturer or seller did any of the following:

- Sold the drug after the effective date of an FDA order recalling the product or withdrawing its approval or substantially altering the terms of approval in a way that would have avoided the claimant's injury
- Intentionally, and in violation of FDA regulations as determined by final agency action, withheld or misrepresented to the FDA information material to drug approval and relevant to the harm caused to the plaintiff
- Made an illegal payment to a government agency employee to secure drug approval

[1] G.S. 99B-6(b)(3).
[2] G.S. 99B-6(b)(4).
[3] G.S. 99B-1(3) defines "Product liability action" to include "any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product."

In addition, the defense would not bar an action brought under the North Carolina False Claims Act, Article 51 of Chapter 1 of the General Statutes[4], if the action is not based on allegations that the drug was not safe or effective or that the manufacturer failed to provide an adequate warning.

EFFECTIVE DATE: The act becomes effective October 1, 2012, and applies to actions commenced on or after that date.

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[4] The False Claims Act allows the recovery of treble damages and imposes civil penalties for obtaining money by submitting or assisting in the submission of false or fraudulent claims to the State. In addition to an action brought by the Attorney General, the act also authorizes a private person, known as a *qui tam* plaintiff, to file an action on behalf of the State and to share in the proceeds of the action under certain circumstances.

The act authorizes the Attorney General, acting through the Medicaid Investigations Unit of the Department of Justice, to issue subpoenas to produce records of corporations or other entities in connection with criminal investigations of health care providers.

The act amends the existing law governing Medicaid provider fraud to make it a Class H felony to obtain money or property by false pretenses, and specifies that a conspiracy to commit those acts is punishable as a Class I felony. The act also makes it unlawful to obstruct an investigation or to conceal, alter, or destroy records with the intent to defraud.